Department of Health & Human Services

Health Care Financing Administration
Region III

Suite 216, The Public Ledger Bldg
150 S. Independence Mall West
Philadelphia, PA 19106-3413

Vincent P. Meconi
Secretary
Delaware Health and Social Services
P.O. Box 906
New Castle, Delaware 19720

Dear Mr. Meconi,

The State of Delaware has requested a home and community-based services waiver authorized under section 1915(c) of the Social Security Act. Specifically, the State has requested a waiver to provide case management, personal care services, respite care services, adult day health, specialized medical equipment and supplies, personal emergency response systems, adult residential care including assisted living, medical nutritional support, and mental health services not included under the State plan to aged and disabled individuals eighteen and over, and individuals under eighteen who meet eligibility criteria for AIDS/HIV waiver services. Eligible individuals would otherwise require care in a nursing facility or hospital. This waiver request has been assigned control number 0360 which should be used in all future correspondence dealing with this request. The State also requested a waiver of section 1902(a)(10)(B), which deals with "comparability" of services.

We have reviewed Delaware's waiver request and have concluded that, as submitted, it does not conform fully to statutory and regulatory requirements. Please provide additional information and make the necessary changes indicated below.

GENERAL

1. Page 1, item 2. The State proposes to serve individuals who meet the hospital or nursing facility (NF) level of care (LOC). Is Delaware proposing to do hospital and NF LOC assessments for **all** individuals applying for the combined (c) waiver determination? How will Delaware distinguish between a hospital or NF LOC? How will this impact enrollees who would only have been evaluated for one level or the other under the current waivers (Elderly/Disabled or Assisted Living who may meet hospital LOC; people with HIV/AIDS who may meet NF LOC)?

2. On page 3, item 8, the State has indicated it will not refuse to offer home and community-based services to any person for whom it expects the cost of waiver services to exceed the cost of NF care. In item 4 of the freedom of choice document submitted by the State in the response to an informal additional information request, the State indicates otherwise. The State will need to determine if it wants to refuse waiver services based on costs and check the

appropriate item on page 3 to reflect its decision. Also, on page 35 of the Case Management attachment, the State indicates it will complete a cost-effectiveness study for each potential waiver enrollee. If it is the State's intent to deny waiver services to individuals exceeding the cost of institutional care, item 8 needs to be checked.

3. On page 8, item 17 of the streamlined waiver format, the State indicates it wishes to provide for an independent assessment of the waiver, and notes below the item that an independent evaluation will be conducted in fulfillment of 1915(b) waiver requirements. Because this is optional, we always ask if the State wants to provide for such an assessment. Please confirm whether Delaware wants to provide for an independent assessment of its 1915(c) waiver in addition to the required 1915 (b) evaluation.

Appendix B

4. On page 1, item a, please check the definition section directly under case management or check "other" and submit your own definition.

5. On page 9, the State indicates it will include specialized medical equipment and supplies. Please explain why these items are not included as a State Plan service under the mandatory home health benefit which includes medical supplies, equipment and appliances suitable for use in the home.

6. On page 14, the State has indicated that limited nursing services such as insulin and other injections and blood sugar monitoring are included under the assisted living program. Is this allowed under Delaware's nurse practice act and does the State intend to include such nursing services under its assisted living service benefit?

7. On page 17, the State has listed medical nutritional support and mental health services under the "other" definition for psychosocial rehabilitation services. We believe these services should be listed under "other waiver services", item s, on page 14. Please explain why the State believes these two services should be included as part of psychosocial rehabilitation services. Psychosocial rehabilitation services are limited to waivers for persons with chronic mental illness. This group of eligibles is not a target population of this waiver.

8. On page 17, the State appears to be restricting medical nutritional support and mental health services to only AIDS/HIV consumers. This is not consistent with HCFA guidance in Olmstead State Medicaid Director Letter Number Four that informs states they may not create separate service packages within a single waiver for different target population sub-groups. Does Delaware plan to make all waiver services available to all waiver recipients if they are assessed as needing such services, per the guidance in Olmstead Letter Four? Additionally, did Delaware include medical nutritional support and mental health services in its calculations of the capitation rate for all three (aged and disabled, assisted living, AIDS/HIV) waiver populations, or only for the AIDS/HIV population?

9. We understand that this new waiver is a combination of Delaware's waivers numbered 0136, 0332 and 4159. We did a side by side comparison of the service packages for each waiver

and noted that homemaker services, included in waiver 0136, were not included in this waiver request. Please explain why this service is provided under 0136 but not in this combined waiver or add the service to this waiver service package if necessary. If the State adds homemaker to the list of services provided under the combined waiver, it will need to revise its appendix G estimates to include this service, and estimated utilization by people enrolled in other waivers. If the State decides not to include this service in the combined waiver, please explain why it was needed under 0136 and not under this waiver.

Appendix B-2

10. Will the new qualifications for case management providers attract agencies with experience serving the target population to the MCOs/PHPs?

11. Is Delaware proposing to eliminate Ryan White Agencies and the Department of Public Health, Division of HIV/AIDS and STDs, as the providers of case management services to people with HIV disease who are, or will be, enrolled through the HCBS waiver?

12. Item 8, specialized DME, the State indicates that the provider type is "DE Medicaid enrolled DME provider." There is no "DME" program under Medicaid and, therefore, the State needs to explain its DME enrollment process and what is meant by "DE Medicaid enrolled DME provider."

13. Item 9, PERS, the State indicates N/A as a provider type. At a minimum, all Medicaid providers must be enrolled under Medicaid to receive payment. Please explain why N/A is indicated in the provider type column.

Attachment to Appendix B-2

14. Non-residential providers of respite care are limited to home health agencies. Please explain why any qualified individual would not be considered a respite care provider.

15. The qualified providers of medical nutritional supports are listed as DME providers and pharmacies. We are concerned that as proposed, the State is unnecessarily restricting providers of medical nutritional supports. For example, we believe that a licensed nutritionist with experience with this population can be a qualified provider of this service. Under a 1915(c) waiver, there can be no restrictions on individual's free choice of qualified providers. Under a 1915(b)(c) combination, this restriction applies only after the (b) waiver overlays the (c) waiver. Prior to that process, the 1915(c) waiver must stand alone and be reviewed and approved absent the restriction of providers authorized under 1915(b).

16. It appears from the Case Management attachment that the case managers contact new enrollees to develop a service plan after they are enrolled in the waiver program. Under the statute and regulations, waiver services must be provided pursuant to a plan of care. Please explain how the State process complies with statutory and regulatory requirements.

17. We have conflict of interest concerns about the case manager being employed by the MCO, overseeing the level of care determinations, developing the plan of care and overseeing the ongoing monitoring of the plan of care. Please explain how the State's proposal does not raise issues of conflict of interest.

18. Pages 36-38 describe the services that can be included in the enrollee's case management service plan. The service "Intensive AIDS Case Management" is listed but not described. On page 32, in the discussion of case management responsibilities, it says that case managers are responsible for efforts to engage the client in care [medical], promoting attendance at [medical] appointments and adherence to [medical] treatment regimens and to encourage client self-sufficiency and empowerment. No other needed medical, social, educational or other appropriate services are listed. In other words, the State has checked the box on page 1 of Appendix B-1: Definition of Services but has subsequently changed the service definition. Is Delaware changing the definition of case management services from an activity which assists individuals in gaining access to needed waiver and other State plan services, as well as needed medical, social, educational, and other appropriate services, regardless of the funding source for the services to which access is gained, to a function assuring medical care coordination?

19. Page 38 in this section describes case manager service plan monitoring, and Appendix E-2 describes the State's process for reviewing plans of care, but the application does not contain Delaware's comprehensive plan to assure quality in this waiver. Please provide Delaware's Quality Assurance Plan for this waiver, or describe how quality services will be assured.

20. How will Delaware assure that individual case management employees in the MCO will have experience with each of the target populations and have the ability to assist clients in accessing needed medical, social, educational, and other appropriate services regardless of funding source (but particularly when they are not services provided by the MCO)? The current HCBS waiver requires that Case Management Providers and their case management employees have experience serving the target population. Please describe how the MCOs/PHPs will be meeting this requirement for each of the waiver populations.

21. On page 41 of the Case Management attachment, it appears that the MCO is the first level of contact for complaints and various grievances. Medicaid beneficiaries must be given the right to a fair hearing on level of care as well as other grievances that affect the amount, duration and scope of waiver services. The fair hearings process is outlined under 42 CFR 431.200-250. The State cannot delegate this authority to a private entity including a MCO. Please explain how the State's process meets Federal requirements.

22. It appears that there are no minimum age or educational requirements for the personal care worker. We would encourage the State to include minimum age requirements. We concur with the criminal background check and would like to know how the State assists the MCO in conducting the criminal background check. Has the State considered requiring a physical to determine if the personal care worker is free from any communicable diseases? Will personal care workers' training include instruction in universal precautions? Finally, it would

be desirable if the State indicates the required amount of hours of training noted in item 11 of the Personal Care attachment.

23. Under medical nutritional support, the State indicates that the case manager requests such support after consulting with medical professionals and that the case manager re-evaluates this service at six-month intervals. Please indicate the type of professional with whom the case manager would consult. We question whether the case manager is the appropriate provider to oversee this service especially since these individuals are fragile and should have professional oversight of the nutritional support. Please explain.

24. It appears the State is including two types of Adult Day Care, social and medical with differing requirements. If so, the State should indicate this in the service definition and also include staffing requirements under each (qualifications of staff).

Appendix C

25. In its October 16, 2000, letter to Sue Davison, the State indicated that it had placed necessary Xs in the appropriate boxes of Appendix C but did not submit these pages. The State should submit the necessary Appendix C pages.

Appendix D

26. On page 1 of this appendix, the State indicates that registered nurses will perform the initial level of care determination. This conflicts with the case management section that indicates that case managers would perform the level of care evaluation and that the case managers do not have to be registered nurses. Please explain.

27. In appendix D-2, the State indicates it will perform a re-evaluation of the level of care required every 6 months. However, the explanation that follows the check off indicates a variety of time limits for re-evaluations. Under Federal regulations, we require at a minimum, a level of care determination annually (see section 42 CFR 441.302(c)(2)). Please revise the process accordingly.

28. This comment applies to the eligibility redetermination section (IV) of the Health Screen. Although the State has submitted informal additional information that states it will follow HCFA's regulation that requires annual re-evaluations, it has not submitted a changed page to indicate that revision and should do so.

29. Please indicate where in the Health Screen the level of care required by the recipient is located. This waiver is being proposed as an alternative to nursing facility and hospital level of care. There should be a clear indication on the form for the level of care an individual requires.

30. Is the Health Screen noted above the same form used by the State to admit patients to hospitals and nursing facilities? If not, the State will need to describe how and why this form differs and give HCFA an assurance that the outcome of the new evaluation form is reliable,

valid, and fully comparable to the form used for hospitals and nursing facilities (42 CFR 441.303(c)(2)).

31. Page 16 of the Health Screen indicates for the AIDS path that an individual must have an AIDS diagnosis. Is this the only requirement for persons with AIDS? How is it determined whether a person with an AIDS diagnosis requires a hospital level of care? The current HIV/AIDS waiver does not have a NF LOC. Will people who are HIV-infected be evaluated for a NF LOC? Please explain why. Also, will Delaware evaluate individuals with HIV/AIDS for a hospital or NF LOC based on their clinical condition or solely on their status under the CDC surveillance criteria? Please explain.

32. In appendix D-4, we could not find the form used to document the individual's choice of institutional or waiver services as noted under item 3.a.

33. On page D-34, item c of 3 indicates that an individual would not be eligible for waiver services if the annual cost of waiver services exceeds institutional care. This statement conflicts with the above noted item 8 where the State indicates they will not refuse enrollment based on cost (see question 2). Please explain. In addition, there is no indication of hospital level of care, which has been checked by the State as a level of care included in this waiver request.

Appendix E

34. It is clear from this appendix that MCOs implement and develop plans of care. Please refer to our comment on conflict of interest under Appendix B-2. Because of the cost savings implied in a 1915(b) waiver and the inability of a recipient to change providers (waiver of section 1902(a)(23)), we have concerns that the provider of services (MCO) establishes the plan of care and implements the service delivery. Please explain.

Appendix G

The following comments pertain to the November 13, 2000, submission.

35. In the November 13, 2000, letter to Sue Davison, the State indicates that the AIDS, Aged and Disabled (A/D), Assisted Living and Acquired Brain Injury (ABI) waivers would be combined into one 1915 (c) waiver. Currently, the ABI waiver is under review and until it has been approved, we cannot determine whether the cost estimates submitted are reasonable.

    If we include the ABI waiver in the combined (c) waiver, the State may have to revise the combined waiver estimates if the approved ABI cost estimates differ from those submitted. We believe the State has options at this point.

    Delaware can continue with the currently approved waivers and have the (b) waiver overlay the currently operating waivers and, upon approval, include the ABI waiver. The State would then amend the (b) waiver to include the ABI waiver.

The State could continue to request the combination of all the waivers and then amend the combined waiver if the estimates included in the approved ABI waiver differ from those submitted in the combined 1915(c) waiver.

36. The State has submitted HCFA 372 forms for the currently operating waivers. The State should use the 372s, when approved, in deriving cost estimates for the combined waiver. These estimates must be for the three-year term of this combined waiver. The State will need to develop two separate cost effectiveness formulas, one for nursing facility level of care and a second for hospital level of care, for each year of the waiver. The State must explain how the cost and utilization for each level of care was developed from the cost and utilization for the appropriate level of care of each of the waivers (AIDS, A/D, Assisted living and ABI). The State would also need to develop a third cost effectiveness formula that combines the nursing facility and hospital levels of care for each year of the waiver. Similar to the process used in developing the cost effectiveness formulas for the separate level of care formulas, the State would need to demonstrate how the cost and utilization for the combined formula was developed from the cost and utilization for each of the waivers. The overall factor G value in the combined formula would be the weighted cost and utilization of hospital and NF levels of care. Each level of care would have a "D chart" that includes the waiver services provided for each year of the three year term and a combined D chart that would be the combined values for each waiver service. We recommend that the State use appendix G of our streamlined waiver format for completing the cost-neutrality demonstration for each level of care and the combined demonstration.

37. We cannot accept cost estimates for the District of Columbia's AIDS waiver as Delaware's basis for calculating the cost of AIDS patients. The AIDS waiver in Delaware is currently operating on its second renewal period and should have approved HCFA forms 372 to base an estimate of costs for services provided under that waiver. We would suggest three years of HCFA form 372 to calculate a trend factor and apply this factor to the latest value submitted on the most recently approved HCFA form 372.

38. In Table 1 of the AIDS waiver estimates, the State submitted estimates for case management and all other services. In deriving factor D, the State will need to list all approved waiver services for each year of the waiver, the unit cost of the service, the definition of the unit (i.e, hour), the number of recipients estimated to receive the service and the units per recipient. Multiplying the number of recipients by the units per recipient per year times the cost per unit should equal the total cost of the service. Please review section 4442.8.C of the State Medicaid Manual that references the above process or review appendix G of the streamlined waiver application for additional assistance.

39. Table 1 for the A/D waiver has the information requested above. However, when reviewing the cost and utilization of these services, we note that personal emergency response systems (PERS) were the single most costly service. We believe that the PERS and personal care services sections may have been reversed. Also, please clarify what the term "medical" means in this chart. Also, the cost of waiver services shown in Table 2 does not equal the cost per recipient we calculated by dividing the total costs in Table1 by 727 recipients. Please explain.

40. Because the ABI waiver is not currently approved and operating, the State must explain how each formula value was developed. If a sample of persons with ABI is used to develop the estimates, Delaware must provide a summary of the sample data.

We believe a conference call to discuss the above issues is merited before the State submits its responses to this request for additional information. We also would be more than happy to meet with the State and assist in its development of cost data for the three years of this waiver request. Please contact Betty Wheeler of my staff at 215-861-4190 to arrange for a conference call or meeting.

Sincerely,

Claudette V. Campbell
Associate Regional Administrator
Division of Medicaid and State Operations

cc: Mary Jean Duckett
Phil Soule'

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